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COLIN G. SANDERCOCK
FOLEY & LARDNER
3000 K ST NW
STE 500
WASHINGTON DC 20007-5109

EXAMINER
SAUNDERS, D

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

063,356

Applicant(s)

BEATTIE

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 11/29/99

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 21-82 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 21-31, 34-82 is/are rejected.

☒ Claim(s) 32-33 is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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The amendment of 11/29/99 has entered no new matter.

The claims pending and under examination are 21-82.

Applicant's response has overcome the previously stated (Paper 9) rejection under 35

U.S.C. 112, 2nd paragraph.

Claims 27-31, 35-37 and 40-82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim contain new matter for reasons of record.

With respect to the issue of *ipsis verbis* support for terms reciting "about", it is proper for the examiner to require such support. Any given value X which is changed to read as "about X" is clearly expanded in scope and thus not properly supported. The mere fact that some dimensions recited on page 8 may have been recited with "about" does not support insertion of "about" with respect to any and all other dimensions.

The recitation of a generic "label" (claims 37, 55, 77) cannot be supported by recitation of certain species of a label. Applicant's urging that page 3 recites "label;" is unconvincing, since page 3 describes the prior art rather than applicant's own invention. Further, even if page 3, line 12 were taken as supporting a "label" generically, it would, at most, support a labeling of DNA for hybridization reactions and not of other members (e.g. antibodies) or of DNA for other purposes (e.g. sequencing).

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dimensions not ltd to micro/nano
The terms "glass" and "silicon" (claims 35, 47, 67) remain unsupported, applicant's

urging that "glass" is supported in original claim 10 is unconvincing, since claim 10 recited "glass.. derivatized with epoxysilane". Applicant's urging regarding the dependency of the claims requires that the substrates be porous is unconvincing. The independent claims merely recite "channels" without dimensions, and "channels" could have macro dimension such that the substrates would not properly be considered porous.

With respect to claim 44, the examiner respectfully points out that specific reasons for the rejection were stated in the paragraph spanning pages 4-5 of Paper 9. The fact that the examiner has indicated that certain specific limitations must be introduced to avoid the new matter rejection is not improper. Applicant has urged (Paper 10, page 5) that one skilled in the art would readily recognize various ways of measuring gene expression other than at the nucleic acid level --e.g. with an antibody. Arguments as to what one of skill might readily recognize pertain to enablement and not to description, and applicant is reminded that these are separate aspects of 112 first paragraph. By not being limited to what the examiner indicated claim 44 must be limited to, applicant has presented a claim which can encompass a new subgenus of assay methods not properly described in the original disclosure.

Microarray
Regarding claim 59, applicant's arguments of what one skilled in the art might be aware of are not relevant to the description of 112 first paragraph. Reference to "RNA" recited at page 4, line 27 is unconvincing since this recites "cellular RNA", which cannot support the broader subgenus "RNA".

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Further with respect to claim 60 the term "polynucleotides" was clearly indicated as being overly broad for the same reason set forth with respect to claim 59; since Example 11 only taught cDNA, the broader subgenus of "polynucleotides" cannot be properly supported. Applicant's urging regarding recitation of "polynucleotide" in original claim 2 is unconvincing, since in claim 2 "polynucleotide refers to reagents fixed on a solid substrate, and not to a method for detecting expression of a gene, as required by base claim 44.

overcome by AF amend.

Regarding claim 63, applicant's arguments again pertain to what one skilled in the art might recognize, rather than to what was described. Applicant's reference to what was recited at page 13, line 29 is unconvincing because this refers to Fig. 6, which is only showing what was specifically done in Example 11. Further page 13, line 29 recites different experimental conditions", while claim 63 recites, more broadly, "different conditions".

For claim 64, applicant has again argued what one skilled in the art would be aware of and has this again failed to realize that enablement and description are separate aspects of 112 first paragraph.

Blasted! got it wrong again!

The examiners notes that the rejection at the bottom of page 5 of Paper 9 was in intended to be in reference to claim ⁶⁶~~65~~, rather than 55. That claim 65 was intended is clear from the context since the examiner referred to a Figure and Example urged by applicant as supporting the language of claim ~~65~~ (Paper 7, page 12). Applicant's traversal presented in Paper 10, page 6 again misses the mark by confusing the enablement and description requirements of 112, first paragraph.

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The rejection of claim 66 pertaining the requirement that the limits of claim 70 be recited therein is maintained. Applicant's urgings pertaining to the disclosure at page 9 are unconvincing because teachings therein are not specifically directed to detecting a sequence variation in a gene, as required in claim 66. Applicant's urgings in Paper 10, page 7 regarding the application of "different samples to two different groups of channels" are unconvincing, because claim 66 requires contacting of "a sample" (line 2), not "different samples".

With respect to claims reciting various dimensions, note the following.

Claims 29, 50, 72 remain unsupported applicant has pointed to page 13, line 7 and page 14, line 10 as supporting. This is unconvincing because the 33 nm diameter recited at page 14, which converts to 0.033 microns, lies outside of the 0.1-10 micron range disclosed at page 13. There was nothing in the disclosure to indicate that a continuum of diameter values between that disclosed on page 14 and the lower limit disclosed at page 13 was intended by applicant. Applicant is thus claiming use of substrates that belong to a new subgenus of substrates.

Claims 31, 51 and 73 remain unsupported because applicant is relying upon the 33 NM dimension disclosed at page 14, line 10 and the 10 um upper dimension disclosed at page 13, line 7. As noted supra for claims 29, 50, 72 these limits were not disclosed as part of a continuum of diameters. Furthermore applicant has urged (Paper 10, page 7) that page 14, lines 28-30 support a thickness range of from 10 um to 1.0 mm. --i.e. a range of from 10 to the minus 5th to 10 to the minus 3rd meter. Page 14, lines 29-30 recite "0.1-1.0 mm" --i.e. 10 to the minus 4th to 10 to the minus 3rd meters. Applicant's claim is thus based on a broader range of thickness than can be

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supported by the specification. Further, it is noted that any value of an inner surface area can result from multiplying an infinitude of circumferences by a infinitude of lengths. Therefore these claims encompass channels having diameters and lengths different from those pointed out by applicant and never recited in the disclosure.

Assuming that applicant's calculations are correct, as presented in Paper 10 at page 8, the examiner has withdrawn the new matter rejection of claims 32, 52 and 74.

Based upon applicant's urgings of Paper 10, page 8 referring to Example 7, the examiner has withdrawn the new matter rejection of claims 34, 54, 76.

*could
W.D.*
Claims 21, 25-31, 34, 37-44, 50-51, 54-60, 66, 72-73 and 76-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Degen et al. in view of Chandler and Brown III et al.

The rejection over this combination of references is maintained because applicant's arguments have not convinced that the applied teachings are irrelevant to the claims.

Applicant has urged that Degen et al. fail to teach coating of the active material in the channels. Applicant is referred to col. 5, line 34-48, which teach the surface of the membrane includes the pores. It is further noted, from applicant's examples, that any agent applied to the nanochannel filters instantly taught would become immobilized on both outer surfaces of the wafer and inner surfaces of the pores. Applicant's urgings regarding the essential impossibility of accomplishing deposition of biologically active material in the pores of the filters of the design of Degen et al. has not been explained or substantiated with any evidence.

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Applicant's urgings pertaining to the failure of Degen et al.'s failure to teach groups of channels are unconvincing. As long as applicant's claims encompass an embodiment in which first and second binding agents are the same, there is nothing that distinguishes "a first group of said channels" from "a second group of said channels"; in fact the membrane could be uniformly coated as in the disclosure of Degen et al.

With respect to the case in which first and second binding agent are different Chandler and Brown III et al. show how to prepare immunoassay filters coated with different reagents in two different regions so as to give distinctive results, depending upon the presence or absence of target analyte in a sample.

Applicant's urgings regarding the deficiencies of Degen et al. are thus unconvincing because they argue that the invention has features which are not, in fact, an actual limitations of the claims, when the terms of the claims are interpreted for the broadest reasonable scope.

Applicant should note that in this action claims 31, 51, 73 are included in the rejection. This is based upon Degen et al. at col. 14, lines 45+ A pore diameter of 0.1 microns (lines 47-48) converts to a circumference ($\pi \times d$) of 3.14×10 to the minus 7th meters. A membrane thickness of 5 mils (line 48) converts to approx. 1.26×10 to the minus 4th meters; multiplying the circumference times the thickness (length of pore) gives a value of 3.96×10 to the minus 11th square meters. It is noted that the 10 square micrometer lower limit of claim 31 converts to 10 to the minus 11th square meters. Thus the pore surface area of each pore within the membranes of Degen et al. is within the range recited by applicant in claims 31, 51, 73.

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Rendering a final rejection in the present action is deemed proper, even though this teaching of Degen et al. was not previously noted. Applicant has not questioned the teachings of any of the dimensions of Degen et al's. filters noted by the examiner. Applicant has instead merely focused on supposed general differences between Degen et al's. and his own filter, and, for reasons noted supra, the examiner finds no such differences. Since no new reference or combination of references has been relied upon presently a final rejection is proper.

Claims 23-24, 35-36, 45-46, 67-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Degen et al. in view of Chandler and Brown III et al. as applied to claims 21, 25-30, 34, 37-43 above, and further in view of Tonucci et al.

This rejection of record is maintained since applicant's traversal has merely focused in deficiencies of the Degen et al., Chandler and Brown III et al. references and argued that Tonucci et al. do not cure these deficiencies, because Tonucci et al's. Filter, like Degen et al's., has no distinct groups of channels. For the reasons indicated supra with respect to Degen et al., Chandler and Brown III et al., the rejection further in view of Tonucci et al. is maintained.

Claim 24, was previously included in this rejection (Paper 9, page 11). Listing of claim 24, on form PTO-326 as objected to was thus clearly in error.

Applicant's urgings filed on 11/29/99 have been considered but are unconvincing.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on M-F from 8:15 a.m. to 4:45 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

Feb. 28, 2000

Mar. 02, 2000

April 5, 2000

David A. Saunders

DAVID SAUNDERS
PRIMARY EXAMINER

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